Translation

PCT/JP2003/010627

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PH-1865-PCT	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP2003/010627	International filing date (*day/month/year*) 22 August 2003 (22.08.2003)	Priority date (*day/month/year*) 18 November 2002 (18.11.2002)
International Patent Classification (IPC) or national classification and IPC A61K 45/00, 39/395, 38/17, A61P 35/00		
Applicant CHUGAI SEIYAKU KABUSHIKI KAISHA		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
22 August 2003 (22.08.2003)	27 April 2004 (27.04.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP2003/010627

I. Basis of the report

1. With regard to the **elements** of the international application:*

☒ the international application as originally filed

☐ the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the claims:

pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☒ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP03/10627

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 8, 9

because:

☒ the said international application, or the said claims Nos. 8, 9 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

The inventions of claims 8 and 9 concern a method for treating the human body by therapy, which does not require an examination by the International Preliminary Examining Authority in accordance with PCT Article 34(4)(a)(i) and Rule 67.1(iv).

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 8, 9.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP03/10627

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	6, 7	YES
	Claims	1-5	NO
Inventive step (IS)	Claims		YES
	Claims	1-7	NO
Industrial applicability (IA)	Claims	1-7	YES
	Claims		NO

2. Citations and explanations

Document 1: Takahiro MIYACHI, "Monoclonal Antibody to Parathyroid Hormone-Related Protein no Nankotsu Nikushu Saibokabu ni Taisuru Saiboshi Yudo Sayo to Bunka Sokushin Sayo," Dai 61 Kai The Japanese Cancer Association Sokai Kiji, August 25, 2002, page 174

Document 2: ZENMYO, M., et al., P21 and parathyroid hormone-related peptide in the growth plate, Calcified Tissue International, 2000, Vol. 67, No. 5, pp. 378-381

Document 3: WO 01/82968 A1 (Chugai Pharmaceutical Co, Ltd.) November 8, 2001, entire document, especially claims 1-13 and page 2, lines 2 to 4; & EP 1283057 A1

Novelty

Claims 1-5

Document 1 states that apoptosis in a chondrosarcoma can be induced by a monoclonal antibody to parathyroid hormone-related peptide, and that this antibody can be used in the treatment of chondroma.

Therefore, document 1 describes the inventions of claims 1-5 of this application.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box V:

Inventive Step
Claims 1-7

Document 3 describes an agent for the treatment of tumors that has as its active ingredient a substance that inhibits the binding between PTHrP and its receptors, and it describes a humanized or chimeric monoclonal antibody to parathyroid hormone-related peptide as that active ingredient (claims 1-13).

This examination finds that prior to the filing date of this application the administration of a humanized or chimeric antibody to decrease the antigenicity of the antibody itself in the bodies of patients was a widely known issue among persons skilled in the art in the field of antibody medications. Therefore, persons skilled in the art could easily adopt the humanized or chimeric antibody described in document 3 in place of the monoclonal antibody described in document 1.

In addition, in reviewing the Detailed Description of the Invention in the Specification of this application, this examination finds that specifying the type of antibody provides no particularly outstanding effect that could not be predicted by persons skilled in the art from the descriptions in documents 1 and 3, and from widely known technology.

Claims 1-7

Document 2 states that PTHrP promotes the growth of chondroma (page 378, Abstract, Fig. 2).

In this case, this examination finds that prior to the filing date of this application not only was it widely known among persons skilled in the art that PTHrP acts on cells via receptors, but also that generally speaking, the inhibition of ligand-receptor binding can inhibit the action of the ligand on cells. Therefore, persons skilled in the art could easily use the monoclonal antibody to parathyroid hormone-related peptide described in document 3, which not only has the effect of inhibiting the action of PTHrP of promoting the growth of chondroma but also has an antitumor effect itself, for the treatment of chondroma.

Thus, this examination finds that the effects of the inventions of claims 1-7 of this application are merely ones that could be predicted by persons skilled in the art from the descriptions in documents 2 and 3, and from widely known technology.